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By Lallance (UNIX)
Date 181/91

A-SW-001035

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TITLE:

CONTROL OF NONCONFORMING ITEMS

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Environmental Management

1.0 PURPOSE

To provide the methods and controls necessary for the reporting, documentation, evaluation, and disposition of items found to not be in conformance with specifications, requirements, prevailing practices, procedures, and standards. These measures are necessary to prevent the inadvertent installation or use of items that are questionable or unusable for Environmental Management (EM) Program activities.

2.0 SCOPE

This procedure applies to all nonconforming items associated with activities performed by EM Department and contractor/supplier personnel in support of EM activities.

3.0 TERMS/DEFINITIONS

- 3.1 Activity An aspect of work, service, operation, condition, or process which impacts quality, safety, or the environment.
- 3.2 Amended Response A change to the disposition that is intended to replace the original disposition or any portion thereof.
- 3.3 Conditional Release An interim disposition that authorizes a process or activity to continue even though a nonconforming condition has been identified.
- 3.4 Disposition The action taken to resolve a nonconforming condition or item and to restore acceptable conditions.
- 3.5 Items Equipment, supplies, or data which impacts quality, safety, or the environment.
- 3.6 NCR Nonconformance Report

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- 3.7 Nonconformance A deficiency in the characteristics, documentation or procedure that renders the quality of an item or activity unacceptable or indeterminate. For EM Department purposes, reference to nonconforming "conditions" or "items" within this procedure includes activity, item, service, data, material, equipment, structure, or condition.
- 3.8 Operability/Safety Assessment An assessment performed to determine if a nonconformance impacts the capability of the system or component to perform its intended function, or exposes operating personnel to potential safety hazards or harms the environment.
- 3.9 Reject/Scrap A disposition that is permitted when an item is determined unsuitable for its intended purpose, is incapable of being reworked or repaired, and will be removed or discontinued from use.
- 3.10 Repair A disposition that authorizes a process of restoring a nonconforming characteristic to a condition such that the capability of an item or condition to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.
- 3.11 Rework A disposition that authorizes a process by which a nonconforming condition or item is made to conform to the original requirements by completion or correction, utilizing existing approved procedures.
- 3.12 Supplemental Response An update to the disposition that provides additional information.
- 3.13 Use-As-Is A disposition that is permitted for a nonconforming condition or item when it can be established that the item is satisfactory for its intended use.

4.0 RESPONSIBILITIES

Unless prohibited by other requirements, responsibilities stated here may be delegated in writing to other individuals within the organization. However, responsibility for the adequacy and effectiveness of the qualification of results remains as stated here.

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- The EM Department Director, or delegate, is responsible for coordinating with the EM Quality Assurance Program Manager (QAPM) to assure Nonconformance Reports (NCRs) are properly reviewed and resolved.
- 4.2 The EM QAPM, or delegate, is responsible for:
 - 1. Coordinating and processing NCRs including tracking and monitoring NCRs, coordinating the use of status tags and conditional releases, assigning disposition responsibilities, evaluating the proposed dispositions for all NCRs, preparing NCR files, and verifying disposition implementation.
 - Designates the EM Department NCR Validator. 2.
 - 3. Designates the EM Department NCR Coordinator.
- EM Department and Contractor/Supplier Personnel are responsible for:
 - Initiating NCRs in accordance with this procedure.
 - Providing dispositions. 2.
 - Implementing dispositions that are authorized by 3. approved procedures and have been assigned by the EM QAPM.
- The EM NCR Coordinator is responsible for:
 - Maintaining an NCR data base and filing system for 1. in-process original NCRs.
 - Assigning a unique NCR tracking number to each validated NCR.
 - 3. Providing issuance of validated NCRs and distribution of copies to the affected organizations.
 - Coordinating and tracking the processing of NCRs. 4.
 - Issuing the dispositioned NCR to the organization 5. responsible for implementing the disposition.

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- Distributing copies of closed NCRs to affected organizations.
- 4.5 The EM NCR Validator is responsible for:
 - Reviews NCR and associated items/activities to determine if the NCR is valid.
 - Discuss any potentially invalid NCR with the initiator as part of the validation process.
 - Transmits valid NCRs to the NCR Coordinator.
 - 4. Transmits invalid NCRs to the NCR master file and to EMD record center per 3-21000-ADM-17.01, Records Management.

5.0 PROCEDURE

5.1 Initiation of a Nonconformance Report

Upon detection of a nonconforming condition, EM Department or contractor/supplier personnel shall initiate an NCR (Attachment 1 and 2).

- 5.1.1 The initiator shall complete the appropriate sections of the NCR (Attachment 2) including pertinent information regarding cited requirements and the actual nonconforming condition.
- 5.1.2 The initiator shall forward the NCR to the EM OAPM for validation.

5.2 Validation and Recording of a Nonconformance Report

- 5.2.1 The EM QAPM shall assign an appropriate individual (Validator) to perform review and validation.
- 5.2.2 The Validator determines if the NCR is valid by review of the stated nonconforming condition and through assuring that the Heading and Nonconformance Block are properly completed and adequately describe the nonconformance.

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If the NCR is determined to be 5.2.2.1 invalid, the Validator will contact the initiator to discuss the reasons. Following discussion, if the NCR is still determined to be invalid, it shall be returned to the initiator and no further action is taken. A copy of the invalidated NCR shall be retained in the NCR master file and transmitted to EMD record center per 3-21000-ADM-17.01, Records

- If the NCR is found to be valid, it 5.2.2.2 shall be forwarded to the EM NCR Coordinator for number assignment, logging, and transmittal to the affected organizations responsible for disposition of the nonconformance and a copy will be forwarded to EMD record Center.
- Valid NCRs shall be entered in the 5.2.2.3 Nonconformance Report Log (Attachment 3) by the QA NCR Coordinator. The NCR number shall take the form of EM NCR-XX-YY, where XX is the current fiscal year and YY is a sequential number starting with 01. All columns of the log shall be filled out for validated NCRs.
- Following validation, the EM QAPM 5.2.2.4 directs the appropriate EM Department Quality Coordinator to apply NCR Status Tags (Attachment

5.3 Identification and Segregation of Nonconforming Items:

Nonconforming items shall be uniquely identified and/or segregated in accordance with the following provisions, unless exempted by the EM QAPM or delegate. The marking or segregation shall not adversely affect the end use of the item.

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- When practical, the EM QAPM, or delegate, with the assistance of the EM Department personnel responsible for the activity, shall segregate the nonconforming item by placing it in a clearly identified and designated hold area until the disposition of the nonconformance is verified.
- 5.3.2 An NCR Status Tag (Attachment 4) shall be filled out and affixed to the item (by a designee of the QAPM) to provide legible identification of the nonconforming condition and to avoid inadvertent use of the item. The NCR Status Tag shall remain with the item until the disposition of the NCR has been completed and verified. If tagging of each item is not practical, the NCR Status Tag shall be applied to the container, package, or to the storage or hold area. If only a portion of an item or activity is nonconforming, the NCR Status Tag shall clearly describe the condition. Note, NCR Status Tags are not QA records and shall be destroyed when removed by the EM QAPM or designee (see Step 5.7.3).
- Work on the item or activity shall be stopped until the disposition is fully approved unless a conditional release has been authorized (see Paragraph 5.4). When only a specific portion of the item or activity is nonconforming, and has been properly identified, then work may proceed on the remaining areas. Any questions regarding the scope of the nonconforming condition and the effect on other areas may be discussed with the EM QAPM.
- 5.3.4 The EM QAPM, or delegate, shall be responsible for removal of the NCR Status Tag, or for notifying responsible personnel to remove the Tag after verification actions are completed (see Paragraph 5.7).
- 5.3.5 If tagging or segregation is not possible, the EM QAPM, or delegate, shall document and

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note the exemption with an explanation on the NCR.

5.4 <u>Conditional Release</u>

A Conditional Release, if requested by the responsible manager, shall be approved by the EM QAPM to allow continuation of an activity or work after consideration of the following conditions, and with justification documented in a conditional release report.

- 5.4.1 The following conditions will be considered for the proposed conditional release and a justification or explanation shall be documented in a memo from the QAPM authorizing Conditional Release Request:
 - 1. The nonconforming item can be removed or corrected at a later date without change, damage, or contamination of the associated data, item, condition, equipment, structures, service, material, or activity.
 - 2. The nonconforming item remains accessible for examination.
 - 3. The nonconforming item is evaluated, and limitation(s) for use of the equipment or system is established.
 - 4. Traceability and identification of the nonconforming item are maintained.
- 5.4.2 The Conditional Release Request memo from the responsible manager will be referenced in or included with the NCR.

5.5 Disposition of NCRs

The EM QAPM shall coordinate with the EM Division Managers to assign personnel to provide a proposed disposition for the NCR within 30 calendar days. This assignment shall be recorded on the NCR, and the NCR shall be forwarded to the assigned personnel for disposition. These personnel shall have access to pertinent background information.

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- 5.5.1 The assigned personnel shall assure that the documented condition is adequately identified and described and shall propose a disposition to resolve the nonconformance. The following information shall be included in the disposition:
 - The proposed disposition actions have been categorized, such as repair, rework, use-as-is, or reject/scrap.
 - 2. The personnel/organization have been identified to implement the disposition and a schedule for completion of actions is included.
 - 3. The root cause and, if appropriate, action(s) to preclude recurrence, have been described.
 - 4. Appropriate technical justification is documented for use-as-is and repair dispositions.
 - 5. Scientific investigation or documents, procedures, plans, work orders, etc., that are to be used to resolve the nonconforming condition have been referenced in the disposition.
 - 6. The technical details for completion of the required actions are accurately and adequately described in the recommended disposition.
 - 7. The proposed action complies with scientific investigation plans or documents, rules, procedures, reports, standards and regulatory requirements.
 - 8. If a change to reflect an as-built condition is appropriate, then the action(s) to change the existing scientific investigation plans or documents, rules, drawings, procedures, reports, standards, etc. has been addressed and cross-referenced.

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- 9. If a conditional release has been requested, the justification has been documented and properly approved.
- 10. Internal interfaces between organizational units and external interfaces between Project participants necessary for executing actions are described.
- 5.5.2 The NCR shall be forwarded (by the QA NCR Coordinator) to the cognizant personnel or Division Manager for review and approval of the proposed disposition.
- The NCR shall then be forwarded to the EM QAPM for review and approval to ensure that appropriate QA requirements have been included. The EM QAPM or delegate shall ensure that the information identified in Paragraph 5.5.1 has been included or considered in the disposition.
- Upon approval, the EM QAPM or delegate, shall forward all NCRs to the personnel responsible for implementation of the dispositions. Copies shall be distributed to the EM Department Director and the cognizant EM Division Managers, as a minimum.

5.6 Implementation of Disposition Actions

Assigned personnel shall implement the dispositions by the completion date as identified in the NCR disposition.

- When additional time is needed to complete actions, the assigned personnel shall provide written notification to the EM QAPM of the adjusted completion date with an explanation of the delay. This extension request shall be submitted on or before the scheduled due date.
- 5.6.2 When changes to the disposition are needed, the assigned personnel shall provide written notification to the EM QAPM.

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- 5.6.2.1 Editorial or administrative corrections or changes shall be recorded on the original NCR and initialed and dated by the person making the changes and by the EM QAPM or delegate.
- 5.6.2.2 Technical or quality changes shall be reviewed and approved by the same organizations or departments that approved the original disposition. The specific change shall be initialed and dated or the disposition approvals may be initialed and dated by each of the responsible organizations.
- 5.6.3 Upon completion of the disposition actions, the responsible personnel shall sign and date the NCR and then notify the EM QAPM of action completion.

5.7 <u>Verification of NCRs</u>

The EM QAPM or delegate shall verify the completed disposition actions through surveillance (Procedure number 3-21000-ADM, 18.02, Surveillance) or a special investigative review.

- 5.7.1 If spare items have been repaired or reworked, the verification shall include a reexamination in accordance with specified procedures and with the original acceptance criteria, unless the NCR disposition established alternate acceptance criteria.
- If the verification is unacceptable, the NCR shall be closed and a new NCR shall be generated in accordance with this procedure to identify the existing condition. The closed NCR shall be updated to reflect the new NCR number, the applicable surveillance or special investigative review, and the NCR shall be signed and dated by the EM QAPM or delegate. The closed NCR shall be distributed to the EM Department Director, the cognizant EM Division Managers, the NCR

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initiator, FQA, and the supplier/contractor, as a minimum. The EM QAPM or delegate shall update the NCR Log and shall notify responsible personnel to update the NCR Status Tag accordingly.

5.7.3 If verification of the disposition and related records is acceptable, the EM QAPM or delegate shall sign and date the NCR and reference the applicable surveillance or special investigative review. Copies of closed NCRs shall be distributed to the initiator, FQA, and the EM Department Director, as a minimum. The EM QAPM or delegate shall notify responsible personnel to remove the NCR Status Tag.

5.8 Records Management

5.8.1 Controlled Documents

None.

5.8.2 Records Center Documents: Records associated with this procedure shall be submitted to the EMD records center in accordance with procedure number 3-21000-ADM, 17.01, Records Management, as identified below:

Nonconformance Report (NCR) Package:

- a. Closed NCRs with supporting documents
- b. Voided NCRs with supporting documents, if appropriate
- Conditional Release Request and c. authorization memos
- d. Completed NCR Logs

6.0 REFERENCES

- 6.1 Superseded Documents: None.
- 6.2 References Cited:

EM Department Administrative Procedure 1-10000-ADM, 15.03, Control of Nonconforming Items.

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EM Department Administrative Procedure 3-21000-ADM. 18.02, Surveillance.

EM Department Administrative Procedure 3-21000-ADM, 17.01, Records Management.

7.0 ATTACHMENTS

Attachment 1: Nonconformance Report (NCR)

Attachment 2: NCR Instruction Sheet Attachment 3: Nonconformance Log

Attachment 4: NCR Status Tag (facsimile)

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ATTACHMENT 1

NONCONFORMANCE REPORT FORM

NONCONFORMANCE REPORT

ENVIRONMEN	ROCKY FLATS ITAL MANAGEME PARTMENT	O.A W7 AU	R No LL ITH #_ OJ NCR No			OF
PROJECT: RESPONSIBLE CO ITEM: REFERENCE:	ORGANIZATION:					
	ANCE DESCRIPTION					
ISSUED BY:	Name	Title	Organiz		DATE	
WORK MANAGE	R/SUPERVISOR			DATE		
INITIAL DISTRIBUTION	DIV, MGR.	EM GAPM	PROJ; MGR.	CONTRACTOR	SITE OA	
DISPOSITION:	USE-AS-IS	REPAIR	REWORK	REJECT	AS-BUILT	CARIUDA
DISPOSITION AP	PROVALS:	DATE	H&S		DATE	
PROJ. MGR.			EM QAPM		DATE	
ENGR		DATE			PATE	
FINAL DISTRIBUTION	DEPT. MGR.	□ ЕМ ОДРМ	PROJ. MGR.	CONTRACTOR	☐ HAS	EM RECORDS
	DIV. MGR.	QUAL, COORD.	CONST. COORD.	ENGR	☐ SITE OA	

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ATTACHMENT 2

NCR INSTRUCTION SHEET

HEADING

- 1. NCR No. FQA NCR Coordinator assigns tracking number after EM QAPM has reviewed NCR and deems it valid.
- Maintenance Work Order (MWO)/Auth. # Initiator enters the MWO or Authorization number shown on the job or project documentation. Nonproject NCR enter N/A.
- 3. Engineering Order # Initiator enters the Engineering Order Number is taken from the MWO Engineering Order. Nonproject NCR enter N/A.
- 4. P.O. # Initiator enters the Purchase Order Number when the NCR pertains to a nonconforming item received at Rocky Flats from a supplier. In all other cases enter N/A.
- 5. Page This pagination field will be completed during the QA review and closure process. It will reflect the total pages included with the closed NCR form.
- Bldg. # Initiator enters the building number in which the nonconforming item is installed or with which it is associated.
- Contractor/Supplier Initiator enters the name of supplier, contractor or responsible work organization who supplied or fabricated or installed the nonconforming item.
- Quality Level Initiator enters the quality level specified in the project or job documentation. In the case of a nonproject NCR, contact the operations/functional manager to obtain the quality level.
- 9. Vital Safety System Completed by the CEO by entering "yes" or "no" based upon evaluation of the nonconforming item.

NONCONFORMANCE BLOCK

10. I.D. # - Initiator enters the serial number or other identification number of the nonconforming item. Enter N/A if the nonconforming item has no identification numbers.

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NCR INSTRUCTION SHEET

- 11. Dwg(s). - Initiator enters the drawing numbers and respective revisions which describe the feature of the item found to be nonconforming.
- Spec./STD(S) Initiator enters the specification or 12. standard, including revision, which details the feature of the item found to be nonconforming.
- NCR Type Completed by the EM QAPM by entering an "X" in the appropriate box after the word which describes the NCR type.
- 14. Item - Initiator enters the description of the item for which the nonconformance has been identified.
- Location Initiator enters a description of the physical 15. location within the building or area where the nonconforming item can be found.
- Nonconformance Description Completed by Initiator by 16. identifying in detail a description of the specific nonconformance. Include specific paragraphs of standards or specifications, drawing details, dates, and other data which specifically outlines the requirements violated by the condition. Essentially, state what the existing condition is and what the requirement documents state the condition should be. Complete the report by section. This section will also include reference to the Resumption Indication Number (RIN) and the corresponding Work Breakdown Structure (WBS) if applicable.
- 17. Operability/Safety Assessment - Completed by the CEO as applicable based on the result of the Operability/Safety Assessment. This block may be N/A'd by the EM QAPM if the item has not been associated with an operating system.
- Operations/Functional Manager Notification Completed by the CEO as applicable based on the result of the Operability/Safety Assessment. This block may be N/A'd by the EM QAPM if not applicable.

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ATTACHMENT 2 (continued)

NCR INSTRUCTION SHEET

- 19. QA Validation completed by the EM QAPM engineer after review, to allow NCR issuance.
- 20. NC Code The EM QAPM enters nonconformance code that best describes the item.

DISPOSITION BLOCK

- 21. Root Cause Completed by the responsible organization who caused the nonconforming condition. This may also be completed by the CEO or the EM QAPM.
- 22. Disposition Completed by the dispositioning engineer.
- 23. Disposition Approval/Concurrences These are the names of the individuals who reviewed the disposition.

QA REVIEW BLOCK

24. QA Comments - This block is completed by the EM QAPM engineer who has reviewed and accepted the NCR disposition. Additional inspection instructions to aid in the verification process may be added in this block.

CLOSE-OUT BLOCK

- 25. Cause Code This block is completed by the EM QAPM based on the root cause detailed in block 21.
- 26. Verification of Disposition Completed by the EM QAPM performing the verification activities.
- 27. Final QA Review Completed by the EM QAPM performing the final review of the Nonconformance Report to allow closure.

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ROCKY FLATS PLANT ENVIRONMENTAL RESTORATION PROGRAM NONCONFORMANCE REPORT LOG

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ATTACHMENT 3

NONCONFORMANCE REPORT LOG

DATE												
STATUS												
DESCRIPTION		-										
RESPONSIBLE ORGANIZATION												
PREPARED BY				-								
NUMBER EM NCR-												
DATE									-			

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